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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,806	02/05/2004	Nikolaus Osterrieder	1/1199-1-C1	5527

28501 7590 10/31/2006

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EXAMINER

BLUMEL, BENJAMIN P

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/772,806

Applicant(s)

OSTERRIEDER ET AL.

Examiner

Benjamin P. Blumel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 8, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6-14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/5/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Notice to Comply.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of invention I drawn to claims 1-17 in the reply filed on September 8, 2006 is acknowledged. Of the claims 1-17, claims 3, 6-14 and 16 are not drawn to the elected invention of a bacterial artificial chromosome, which expresses the entire genome of EHV-1 RacH strain with glycoprotein gM deleted. Therefore, these claims are withdrawn from consideration. Claims 1, 2, 4, 5, 15 and 17 are examined in this Office Action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 5, 2004 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Objections

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The specification is objected to because each nucleic acid sequence shown in Table 1 does not contain a specific SEQ ID No.:

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Applicants must comply with sequence rules in order to be considered a complete response to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1,4 and 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant invention is drawn to a bacterial artificial chromosome vector comprising essentially the entire genome of EHV-1 RacH strain, accession no. ECACC 01032704.

Deposit rules require a date of deposit in the specification in order to comply with 37 CFR 1.809 (d).

It is apparent that the bacterial artificial chromosome vector that expresses essentially the entire genome of EHV-1 RacH strain of the claimed invention is required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the bacterial artificial chromosome vector. See 37 CFR 1.802. One cannot practice the claimed invention without a bacterial artificial chromosome that expresses the entire genome of the virus. One cannot determine whether the genome of the virus is completely expressed without access to the bacterial artificial chromosome vector. Therefore, access to bacterial artificial chromosome vector of the claimed invention is required to practice the invention. The specification does not provide a repeatable method for the bacterial artificial chromosome vector of the claimed invention without access to the bacterial artificial chromosome vector of the claimed invention and it does not appear to be readily available material.

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Deposit of the bacterial artificial chromosome vector of the claimed invention in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGregor et al. (Molecular Genetics and Metabolism, 2001) in view of Neubauer et al (Virology, 1997).

The instant invention is drawn to a polynucleotide encoding a bacterial artificial chromosome (BAC) accession No. ECACC 01032704, that comprises the genome of EHV-1 RacH that lacks glycoprotein M (gM).

McGregor et al. reviews the discoveries of BAC as a tool to express the genome of numerous herpes viruses, such as HSV-1, which is an alphaherpesvirus. One key feature of BAC is the ability to clone and express large sequences of up to 600kbp, for example, the 230kbp genome of murine cytomegalovirus, a betaherpesvirus. In addition, this property of BAC provides the ability to observe the effects of mutations on viral functions. Furthermore, McGregor et al. discusses therapeutic properties, which mutated viruses may possess with regard to virulence, immunogenicity and overall safety in vaccination of at risk populations. However, McGregor et al. do not teach the BAC of accession no. ECACC 01032704, which expresses EHV-1 RacH or a BAC that expresses a gM deficient EHV-1 RacH virus. *See pages 8-13.*

Neubauer et al. teaches comparing vaccination protection from EHV-1 challenge. A series of vaccinations were conducted on mice including wild type and mutant EHV-1 strains RacL11 and RacH. Each mutated strain contained an interruption of the gM or gB glycoprotein gene with the LacZ gene. Mice (BALB/c) vaccinated with EHV-1 RacL11 or RacH mutants were shown to have protective immunity when challenged. For example, groups of mice were vaccinated with parental strains or with mutants thereof, 25 days later, RacL11 was administered

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to each group, bodyweight was monitored for the following 11 days. The bodyweight of the mock-infected mouse group decreased 20% by day 4. In addition, the viral loads from lung tissues of the negative control were 4.6×10^3 (avg.) as compared to 50 PFU/lung or less among pre-vaccinated groups. Furthermore, Neubauer et al. discuss potential success of EHV-1 RacL11 and RacH mutants, which do not express gM or gB, in providing protective immunity to equid subjects. Especially, an EHV-1 RacH strain, that lacks gM as an effective but safe vaccine and expression vector. *See pages 36, 37, 41, 43, 44 and figure 4.*

It would have been obvious to one of ordinary skill in the art to modify the composition taught by McGregor et al. in order to express related alphaherpesviruses in a BAC, thereby providing a BAC, which expresses a specific glycoprotein M deficient strain of EHV-1, such as RacH. One would have been motivated to do so, given the suggestion by McGregor et al. that the composition be used to express entire recombinant genomes of herpesviruses up to 600kbp. There would have been a reasonable expectation of success, given the knowledge that glycoprotein M and B deficient EHV-1 viruses maintain wild type life cycles and immunogenicity, as taught by Neubauer et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Summary

No claims are allowed.

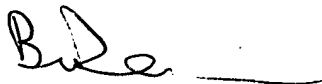
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Benjamin Blumel
Patent Examiner



**BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

Notice to Comply	Application No. 10/772,806	Applicant(s) Osterreider et al.	
	Examiner Benjamin Blumel	Art Unit 1648	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: The disclosure is missing SEQ ID NO:s, see attached Action under Objections.

Applicant Must Provide:

- ☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**
- ☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923

For CRF Submission Help, call (703) 308-4212 or 308-2923

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